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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,330	04/22/2005	Jean-Louis Assie	401/1/009	1760

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SUITE 419
HACKENSACK, NJ 07601

EXAMINER

PICKETT, JOHN G

ART UNIT	PAPER NUMBER
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3728

MAIL DATE	DELIVERY MODE
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08/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/532,330		ASSIE ET AL.	
	Examiner		Art Unit	
	Greg Pickett		3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action acknowledges the Preliminary Amendment filed 22 April 2005. Claims 1-10 are pending in the application.

Information Disclosure Statement

2. The listing of references in the specification (e.g. FR 99/14729) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The references cited in the Search Report of PCT/FR03/03239 have been fully considered; the references appear to be listed on the IDS of 22 April 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bailey (US 3,826,259).

Claim 1: Bailey discloses a single-use package comprising a protective cover made of two separable parts 20 & 30 of leak-proof material (Col. 2, lines 49-50), and a breakable leak-proof blister 11 containing a dose of a substance 21, wherein the blister is attached to an inside face of part 20. As the package of Bailey is a single-use device, the dosage is considered a single dose.

4. Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleury (US 6,695,515).

Claim 1: Fleury discloses a single-use package comprising a protective cover made of two separable parts A & B of leak-proof material (see for example Col. 1, lines 34-38), and a breakable blister A1 containing one dose of substance A1' attached to an inside surface of part B.

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Claim 9: Fleury discloses a peel-off cover C containing adhesive dressing D affixed to an outside surface of cover part B.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (US 5,562,642) in view of Gruenbacher et al (US 6,547,468).

Claims 1 and 2: In Figures 1 & 2, Smith discloses a single-use packaging 10 comprising a protective cover made of two separable parts 12 & 14 of leak-proof material (see Col. 8, lines 35-42). Smith discloses an applicator 20 impregnated with a dose of substance (see for example Col. 10, lines 19-30) fixed on an inside face of the cover part 12, but does not disclose the applicator as a pouch with breakable blister.

Gruenbacher teaches an applicator comprising a pouch 10, applicator 15, and blister 12 housed within the pouch for the controlled release of the substance (see for example Col. 2, lines 56-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the applicator pads of Smith with the applicator of Gruenbacher in order to provide controlled release of the substance.

Claim 3: Gruenbacher discloses a pouch with a first part of flexible material 25 and a second part of flexible, porous material 15 united by closed junction 13/16 with blister 12 held captive between the parts. Smith teaches the applicator fixed to the inside face of cover part 12. To enable application of the substance, one of ordinary skill in the art would have found it obvious to mount the impermeable first part 25 of Gruenbacher to the inside face of Smith.

Claims 5-7: Smith teaches closed outline junction line 34 surrounding the applicator in an area significantly greater than the applicator area 20, which is substantially centered. Outline junction 34 permits peelable separation and is a heat seal or adhesive (see for example Col. 9, lines 59-62). It would have been obvious to one of ordinary skill in the art to maintain this arrangement when the applicator pad 20 of Smith is replaced with pouch 10 of Gruenbacher.

Claim 8: Smith discloses pull-tabs 60 & 62.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith-Gruenbacher as applied to claim 3 above, and further in view of Kerch et al (US 4,762,124).

Smith-Gruenbacher as applied to claim 3 above, discloses the claimed invention except for the cotton wool inside the pouch.

Kerch teaches the provision of cotton wool 20 inside an applicator 10 with a permeable membrane 22 for the purpose of retaining large quantities of liquid in measured amounts (see for example Col. 4, lines 42-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide cotton wool inside the pouch of Smith-Gruenbacher in order to retain large quantities of liquid in measured amounts.

7. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith-Gruenbacher as applied to claim 1 above, and further in view of Fleury (US 6,695,515) and Frank (US 5,511,689).

Smith-Gruenbacher, as applied to claim 1 above, discloses the claimed invention except for the adhesive dressing.

Fleury suggests the provision of an adhesive dressing D on an applicator package for covering a wound after it has been disinfected (see for example Col. 2, lines 16-18).

Frank teaches an adhesive dressing 1 and cover 4 applicable to the external surface of a film 6 with the outside surface of dressing 1 weakly secured to an inside face of cover 4; cover 4 is affixed to mounting film 6. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an adhesive dressing as taught by Frank to a package of Smith-Gruenbacher for covering a wound after it has been disinfected as suggested by Fleury.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of

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compending Application No. 10/539,266 in view of Gruenbacher et al (US 6,547,468).

Claims 1-12 of compending Application No. 10/539,266 merely lack the breakable blister.

Gruenbacher teaches an applicator comprising a pouch 10 with blister 12 housed within the pouch for the controlled release of the substance (see for example Col. 2, lines 56-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the applicator of claims 1-12 of compending Application No. 10/539,266 with a blister as taught by Gruenbacher in order to provide controlled release of the substance.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Greg Pickett whose telephone number is 571-272-4560. The examiner can normally be reached on Mon-Fri, 11:30 AM - 8:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Greg Pickett/
Examiner
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